



**Technical
Specification**

ISO/TS 27790

**Health informatics — Document
registry framework**

Informatique de santé — Cadre d'enregistrement de document

**Second edition
2026-03**

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/TS 27790:2009), which has been technically revised.

The main changes are as follows:

- Annex A was removed as only one country, the Republic of Korea, was included in it originally;
- updated to reflect the latest changes in the IHE document sharing profiles, such as the addition of Mobile Health Document (MHD), addition of IHE Integration Profile, Mobile Health Document Sharing (MHDS) IHE Integration Profile, and corrections to Cross-Enterprise Document Sharing (XDS.b) IHE Integration Profile. These profiles facilitate the registration, distribution and access across health enterprises of patient electronic health records.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Development and implementation of electronic health records (EHR) are rapidly progressing around the world. An appropriate deployment of EHR will enhance various aspects of healthcare delivery, such as safety and efficiency. EHR are thought to enable the provision of essential care information to providers at point-of-care through information and telecommunications technologies. This includes a broad spectrum of capabilities including acquisition, storage, presentation and management of patient information (represented in different digital forms such as video, audio or data) and communication of this information between care facilities with the use of communications links.

Recent development of health information exchange where the patients' EHR are accessed securely whenever necessary (sharing EHR information at point-of-care and by the consumer citizen) requires that electronic health records of an individual, although they originate from various health-related subjects distributed over space and time, remain accessible irrespective of their centralized or distributed storage. The use of centralized registry systems pointing to such records can greatly facilitate the discovery of their locations to allow effective access to the appropriate and secured EHR.

Many organizations with operational large-scale deployments implement this foundational approach in sharing health data among existing systems as a simple and effective service. However, these initial projects identified several issues or gaps in document sharing that limited their deployment (e.g. lack of standardization, fragmentation of health data, difficulty in locating distributed records, inconsistencies in abilities to search records from many care delivery organization). The proposed framework addresses such issues by offering consistent search data among data stored with various degrees of granularity. There have been enough operational deployments across more than 20 countries with hundreds of different health information systems and several millions of clinical documents shared to confirm the robustness and efficiency of such a standards-based document sharing framework.

This document is targeted at policy makers, architects of national ehealth infrastructure, health IT product managers and designers. It describes the principles and specification of interoperability needed to support a registry system for locating and accessing records grouped into shared documents. The supported documents may contain any type of person-centric health information, whether structured (e.g. coded patient summary, numeric lab results) or unstructured (e.g. scanned images, free-text documents), depending on the source standard for their content. The clinical document architecture (CDA), the Fast Healthcare Interoperability Resources (FHIR), Digital Imaging and Communications in Medicine (DICOM) are standards that are likely companions to this document. This document does not address the security and privacy considerations in detail but refers to related interoperability standards and profiles designed to be used in conjunction. The document does not mandate a specific method or technology but rather provides a coherent inclusive description of principles and practices that can facilitate the formulation of policies and governance practices locally or nationally.

The web services-based registry framework includes a document registry and associated repository to allow the sharing of any form of health documents including HL7 CDA, FHIR documents and DICOM objects.

The registry framework specializes in health two different application programming interfaces (API):

- The W3C Web Services Standards, ISO 15000 (ebXML registry standards) and OASIS ebXML Registry Information Model 3.0 through the use of the IHE Cross-Enterprise Document Sharing (XDS) from the Integrating the Healthcare Enterprise (IHE) Information Technology Infrastructure (ITI) technical framework, summarizing from the Cross-Enterprise Document Sharing (XDS) Profile:

“The Cross-Enterprise Document Sharing IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient and citizen electronic health records. Cross-Enterprise Document Sharing (XDS) is focused on providing a standards-based specification for managing the sharing of documents between all health enterprises, ranging from private physician offices to clinics to acute care in-patient facilities to personal health record systems. The XDS IHE Integration Profile assumes that these enterprises belong to one or more affinity domains. An affinity domain is a group of healthcare enterprises that have agreed to work together using a common set of policies and that share a common registry infrastructure.”

- The HL7 FHIR Document Reference resources through the use of the IHE Mobile access to Health Document (MHD) or the more extensive IHE Mobile Health Document Sharing (MHDS) from the Integrating the Healthcare Enterprise (IHE) Information Technology Infrastructure (ITI) technical framework, summarizing from the Mobile access to Health Document Sharing (MHDS) Profile:

“The Mobile access to Health Documents (MHD^[37]) Profile defines a standardized API for mobile devices, like smartphones and tablets, to share health documents. It simplifies the document sharing process originally used in XDS and XCA, making it easier for mobile and simple systems to submit, query, and retrieve health documents.

The MHDS^[38] Profile provides a framework for communities to exchange health information by using a combination of other IHE profiles. It covers essential functions like patient identification, document management and storage, and privacy and security, all to ensure a standardized and interoperable approach to health information sharing.”

This document also references a number of companion standards-based specifications^[9] that offer optional extensions to enhance the basic capabilities offered by IHE XDS, namely a series of security-related and privacy-related IHE profiles, such as Patient Identification Cross-Referencing (PIX^[9]), Patient Demographics Query (PDQ^[9]), Basic Patient Privacy Consent (BPPC^[9]), and Cross-Enterprise User Assertion (XUA^[9]).

NOTE The use of IHE Audit trail and Node Authentication (ATNA) as well as Consistent Time (CT) is required as part of IHE XDS. These Profiles are therefore not listed above.

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Health informatics — Document registry framework

1 Scope

This document specifies a general-purpose document registry framework for transmitting, storing and utilizing documents in clinical and personalized health environments. It is quite broad in its applicability to realise the goal of sharing health-related documents spanning a broad spectrum of health domains such as healthcare specialities covering laboratory, cardiology, eye care, etc. and the many areas of personalized health.

This document also supports shared document registration and retrieval via the federation of documents' registries (IHE Cross-Community Access) in terms of individual users to reduce health information extrusion possibilities.

This document supports the sharing of documents of any standardized content in the context of healthcare and well-being. It describes the means of locating and accessing shared documents among a diverse set of health organizations. It is designed to leverage existing health informatics for structuring and semantically rich health information, if so desired. It does not require the development of new health informatics standards.

2 Normative references

There are no normative references in the document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

actor

user of the system-of-interest interacting with the system in a particular usage context or role

3.2

architecture

set of design artefacts or descriptive representations that are relevant for describing an object such that it can be produced to requirements (quality) as well as maintained over the period of its useful life (change)

3.3

authentication

act of verifying the claimed identity of an entity

[SOURCE: ISO/IEC 10181-2:1996, 3.3, modified — “provision of assurance” was changed to “act of verifying”]

3.4

authorization

granting of rights, including the granting of access based on access rights

[SOURCE: ISO 7498-2:1989, 3.3.10]